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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,505	10/14/2003	Lijun Sun	61223(50586)	3546

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EXAMINER

NOLAN, JASON MICHAEL

ART UNIT PAPER NUMBER

1626

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/686,505	Applicant(s) SUN ET AL.	
	Examiner Jason M. Nolan, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 26-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

**Claims 1-38** are currently pending in the instant application.

### *Priority*

Applicant's claim for priority of U.S. Provisional Patent Application 60/418,984, filed October 15, 2002 is acknowledged.

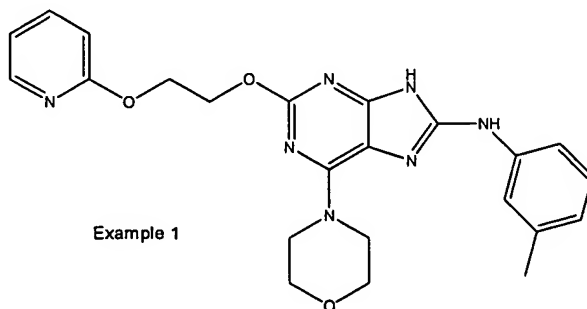
### *Information Disclosure Statement*

Applicant's information disclosure statements (IDS), filed on January 3, 2005 and February 2, 2006, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

### *Response to Restriction*

Applicants' election with traverse of **Group I, Claims 1-25**, drawn to compounds according to the formula of Claim 1, is acknowledged.

Furthermore, applicants' election of the specific compound in which:  $R_1 = m\text{-tolyl}$ ;  $R_2 = R_4 = R_5 = H$  for each occurrence;  $R_3 = 2\text{-pyridin-2-yloxy}$ ;  $A = NH$ ;  $B = N$ ;  $X = NH$ ;  $Y = O$ ;  $Z = N$ ;  $W = O$ ; and  $n = 2$ . This is the compound {6-morpholin-4-yl-2-[2-pyridin-2-yloxy)-ethoxy]-9H-purin-9-yl}- $m$ -tolyl-amine, disclosed in Example 1 of the specification and shown below, classified in class 544, subclass 118, is acknowledged.



Example 1

Examiner also acknowledges applicants' request to reconsider the Restriction Requirement on the grounds that consideration and examination of the groups specified in the Restriction should not impose an undue burden.

Inventions I and II are related as products and methods of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the method for using the product as claimed can be practiced with another materially different products or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, the method for using the product as claimed can be practiced with another materially different products. For example, treating rheumatoid arthritis can be practiced with a variety of commercially available products such as Alleve, Tylenol, or Advil.

In addition, because of the plethora of classes and subclasses encompassed by the scope of the compounds claimed within each of the Groups, a serious burden is imposed on the Examiner to perform a complete search of the defined areas. The compounds of Claim 1 contain core variables **U**, **V**, **A**, and **B**; in which **A** can be O, S, S(O), S(O)<sub>2</sub>, or NR<sup>e</sup>; **B** can be N or CR<sup>f</sup>; and each of **U** and **V**, independently, can be N or CR. The compounds according to the formula of Claim 1 can represent at least 24 patentably distinct cores and the Examiner is faced with a serious burden to do a comprehensive search on these cores.

Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

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Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

As previously stated in the restriction requirement, in accordance with M.P.E.P. 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of method of use claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until such time, a restriction between product claims and process is deemed proper.

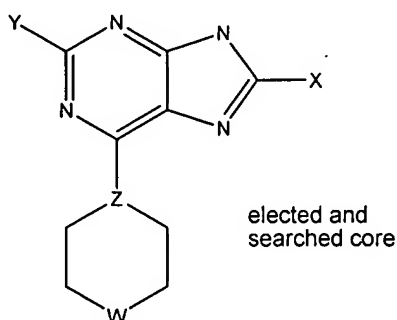
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Status of the Claims***

**Claims 1-38** are pending in this application. **Claims 1-25 (in part) & 26-38** are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

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The scope of the invention of the elected subject matter: compounds of the Formula (I) in Claim 1 and the species in Example 1 shown above; and the examined subject matter is as follows:



in which **X**, **Y**, **Z**, and **W** are as defined in Claim 1. This includes **Claims 1-25 (in part)**.

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of **Claims 1-25 (in part)** is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions.

The scope of the invention of the *non*-elected and *non*-examined subject matter is as follows: compounds of the Formula (I) in Claim 1, wherein **U**, **V**, **A**, and **B** are not all N. The withdrawn compounds contain the variety of cores, which are patentably distinct from the elected and examined core, and are chemically recognized to differ in structure, function, and reactivity. Therefore, the subject matter which has been withdrawn from consideration as being *non*-elected subject matter materially differs in structure and composition from the elected/examined subject matter so that a reference which anticipates the elected/examined subject matter would not render obvious the *non*-elected subject matter.

This recognized chemical diversity of the functional groups can be seen by the various classifications of these structural cores in the U.S. classification system, i.e. class 546 for 6-membered heterocyclic rings with one nitrogen as the only heteroatom, class 548 for 5-membered heterocyclic rings with one nitrogen as the only heteroatom, and class 549 for 5-membered heterocyclic rings with non-nitrogen heteroatoms, etc. The fields of search required for the *non*-elected versus the elected compounds are not coextensive. All compounds falling outside the class of the selected compound are heretofore directed to *non*-elected subject matter and are withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b).

Regarding the scope of compounds set forth above, *the compounds are free of prior art and are drawn to allowable subject matter*. Amendments to the claims in order to conform with the scope set forth above and cancellation of *non*-elected subject matter will put Applicant's claimed invention in condition for allowance. Applicant has the right to file divisional applications on the remaining subject matter.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Objections***

**Claims 1-25 (in part)** are objected to for containing *non*-elected subject matter.

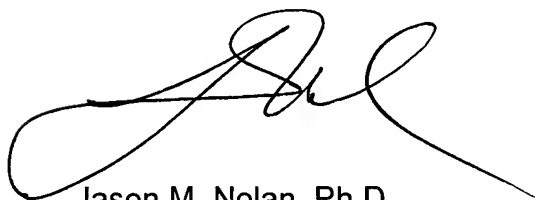
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***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM).

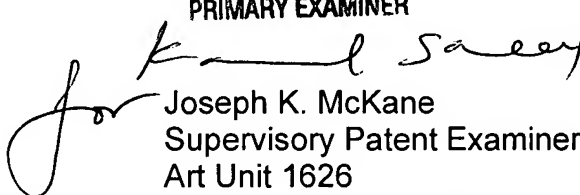
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is **(571) 273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jason M. Nolan, Ph.D.  
Examiner  
Art Unit 1626

KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER



Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626  
Date: February 3, 2006